



兹证明

江苏华益科技有限公司埃索托普分公司

统一社会信用代码：913205817658986684

经营地址：江苏省常熟经济开发区氟化学工业园

注册地址：江苏省常熟经济开发区氟化学工业园

的质量管理体系适用于

用于 PET（正电子发射断层扫描仪）显像剂装载用无菌瓶、MX 卡套、IFP（集成流体处理器）卡套的加工和销售

已经 NQA 根据标准

ISO 13485:2016

审核和注册

注册要求组织必须按照上述标准保持其质量管理体系，并由 NQA 进行监督。
获证组织必须定期接受监督审核并经审核合格，此证书方继续有效。
本证书信息可在国家认证认可监督管理委员会官方网站（www.cnca.gov.cn）上查询
SNQA 查询网站：www.snqa.com.cn


总经理

证书号：**46584**

初次发证日期：2019年06月28日
上一认证周期：2022年06月28日
本次审核日期：2022年06月23日
本次发证日期：2022年07月04日
证书有效期至：2025年06月28日



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This is to certify that the Quality Management System of

Huayi Isotopes Co. (a division of Jiangsu Huayi Technology Co., Ltd.)

Unified Social Credit Code: 913205817658986684

Operation Address: Fluorine Chemical Industrial Park, Changshu Economic Development Zone, Changshu City, Jiangsu Province, China

Registered Address: Fluorine Chemical Industrial Park, Changshu Economic Development Zone, Changshu City, Jiangsu Province, China

applicable to

The production and sales of sterile vials used for PET (positron emission tomography) radioactive tracers, MX cassettes and IFP (integrated fluid processor) cassettes

has been assessed and registered by NQA against the provisions of

ISO 13485:2016

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by NQA.

Certified Clients shall accept regular surveillance assessments, the validity of certificates shall be maintained for the positive result of audit.

The information of this certificate can be checked on CNCA's website (www.cnca.gov.cn)
SNQA's website: www.snqa.com.cn

Managing Director

Certificate Number: **46584**

Issue Date: 28 June 2019

Previous Certificate Expiry: 28 June 2022

The Latest Audit Date: 23 June 2022

Reissue Date: 04 July 2022

Valid Until: 28 June 2025



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The use of the UKAS Accreditation Mark indicates accreditation in respect of those activities covered by the accreditation certificate number 015 held by NQA.

NQA is a trading name of NQA Certification Limited, Registration No 09351758. Registered Office: Warwick House, Houghton Hall Park, Houghton Regis, Dunstable, LU5 5ZX, UK.

This certificate is the property of NQA and must be returned on request.

Shanghai NQA Certification Co., Ltd. Address: Room 2201, 958 Lujiazui Ring Road, China (Shanghai) Pilot Free Trade Zone.